

108TH CONGRESS
1ST SESSION

H. R. 2427

IN THE SENATE OF THE UNITED STATES

JULY 25 (legislative day, JULY 21), 2003

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To authorize the Secretary of Health and Human Services
to promulgate regulations for the reimportation of pre-
scription drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Pharmaceutical Mar-
3 ket Access Act of 2003”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Americans unjustly pay up to 1000 percent
7 more to fill their prescriptions than consumers in
8 other countries.

9 (2) The United States is the world’s largest
10 market for pharmaceuticals yet consumers still pay
11 the world’s highest prices.

12 (3) An unaffordable drug is neither safe nor ef-
13 fective. Allowing and structuring the importation of
14 prescription drugs ensures access to affordable
15 drugs, thus providing a level of safety to American
16 consumers they do not currently enjoy.

17 (4) According to the Congressional Budget Of-
18 fice, American seniors alone will spend \$1.8 trillion
19 dollars on pharmaceuticals over the next ten years.

20 (5) Allowing open pharmaceutical markets
21 could save American consumers at least \$635 billion
22 of their own money each year.

23 **SEC. 3. PURPOSES.**

24 The purposes of this Act are as follows:

25 (1) To give all Americans immediate relief from
26 the outrageously high cost of pharmaceuticals.

1 (2) To reverse the perverse economics of the
2 American pharmaceutical markets.

3 (3) To allow the importation of drugs only if
4 the drugs and the facilities where they are manufac-
5 tured are approved by the Food and Drug Adminis-
6 tration, and to exclude pharmaceutical narcotics.

7 (4) To require that imported prescription drugs
8 be packaged and shipped using counterfeit-resistant
9 technologies approved by the Bureau of Engraving
10 and Printing (technologies similar to those used to
11 secure United States currency).

12 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS.**

13 Section 804 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 384) is amended—

15 (1) in subsection (a)—

16 (A) by striking “The Secretary” and in-
17 serting “Not later than 180 days after the date
18 of the enactment of the Pharmaceutical Market
19 Access Act of 2003, the Secretary”; and

20 (B) by striking “pharmacists and whole-
21 salers” and inserting “pharmacists, wholesalers,
22 and qualifying individuals”;

23 (2) in subsection (b)—

24 (A) by amending paragraph (1) to read as
25 follows:

1 “(1) require that each covered product imported
2 pursuant to such subsection complies with sections
3 501, 502, and 505, and other applicable require-
4 ments of this Act; and”;

5 (B) in paragraph (2), by striking “, includ-
6 ing subsection (d); and” and inserting a period;
7 and

8 (C) by striking paragraph (3);

9 (3) in subsection (c), by inserting “by phar-
10 macists and wholesalers (but not qualifying individ-
11 uals)” after “importation of covered products”;

12 (4) in subsection (d)—

13 (A) by striking paragraphs (3) and (10);

14 (B) in paragraph (5), by striking “, includ-
15 ing the professional license number of the im-
16 porter, if any”;

17 (C) in paragraph (6)—

18 (i) in subparagraph (C), by inserting
19 “(if required under subsection (e))” before
20 the period;

21 (ii) in subparagraph (D), by inserting
22 “(if required under subsection (e))” before
23 the period; and

24 (iii) in subparagraph (E), by striking
25 “labeling”;

1 (D) in paragraph (7)—

2 (i) in subparagraph (A), by inserting
3 “(if required under subsection (e))” before
4 the period; and

5 (ii) by amending subparagraph (B) to
6 read as follows:

7 “(B) Certification from the importer or
8 manufacturer of such product that the product
9 meets all requirements of this Act.”; and

10 (E) by redesignating paragraphs (4)
11 through (9) as paragraphs (3) through (8), re-
12 spectively;

13 (5) by amending subsection (e) to read as fol-
14 lows:

15 “(e) TESTING.—

16 “(1) IN GENERAL.—Subject to paragraph (2),
17 regulations under subsection (a) shall require that
18 testing referred to in paragraphs (5) through (7) of
19 subsection (d) be conducted by the importer of the
20 covered product, unless the covered product is a pre-
21 scription drug subject to the requirements of section
22 505B for counterfeit-resistant technologies.

23 “(2) EXCEPTION.—The testing requirements of
24 paragraphs (5) through (7) of subsection (d) shall

1 not apply to an importer unless the importer is a
2 wholesaler.”;

3 (6) in subsection (f), by striking “or designated
4 by the Secretary, subject to such limitations as the
5 Secretary determines to be appropriate to protect
6 the public health”;

7 (7) in subsection (g)—

8 (A) by striking “counterfeit or”; and

9 (B) by striking “and the Secretary deter-
10 mines that the public is adequately protected
11 from counterfeit and violative covered products
12 being imported pursuant to subsection (a)”;

13 (8) in subsection (i)(1)—

14 (A) by amending subparagraph (A) to read
15 as follows:

16 “(A) IN GENERAL.—The Secretary shall
17 conduct, or contract with an entity to conduct,
18 a study on the imports permitted pursuant to
19 subsection (a), including consideration of the
20 information received under subsection (d). In
21 conducting such study, the Secretary or entity
22 shall evaluate the compliance of importers with
23 regulations under subsection (a), and the inci-
24 dence of shipments pursuant to such sub-
25 section, if any, that have been determined to be

misbranded or adulterated, and determine how such compliance contrasts with the incidence of shipments of prescription drugs transported within the United States that have been determined to be misbranded or adulterated.”; and

(B) in subparagraph (B), by striking “Not later than 2 years after the effective date of final regulations under subsection (a),” and inserting “Not later than 18 months after the date of the enactment of the Pharmaceutical Market Access Act of 2003,”;

(9) in subsection (k)(2)—

(A) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

(B) by inserting after subparagraph (C) the following:

“(D) The term ‘qualifying individual’ means an individual who is not a pharmacist or a wholesaler. ”; and

(10) by striking subsections (l) and (m).

**SEC. 5. USE OF COUNTERFEIT-RESISTANT TECHNOLOGIES
TO PREVENT COUNTERFEITING.**

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming

1 drugs and devices to be misbranded) is amended by adding
 2 at the end the following:

3 “(w) If it is a drug subject to section 503(b), unless
 4 the packaging of such drug complies with the require-
 5 ments of section 505B for counterfeit-resistant tech-
 6 nologies.”.

7 (b) REQUIREMENTS.—Title V of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 9 ed by inserting after section 505A the following:

10 **“SEC. 505B. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

11 “(a) INCORPORATION OF COUNTERFEIT-RESISTANT
 12 TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-
 13 AGING.—The Secretary shall require that the packaging
 14 of any drug subject to section 503(b) incorporate—

15 “(1) overt optically variable counterfeit-resist-
 16 ant technologies that are described in subsection (b)
 17 and comply with the standards of subsection (c); or

18 “(2) technologies that have an equivalent func-
 19 tion of security, as determined by the Secretary.

20 “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-
 21 scribed in this subsection—

22 “(1) shall be visible to the naked eye, providing
 23 for visual identification of product authenticity with-
 24 out the need for readers, microscopes, lighting de-
 25 vices, or scanners;

1 “(2) shall be similar to that used by the Bureau
2 of Engraving and Printing to secure United States
3 currency;

4 “(3) shall be manufactured and distributed in a
5 highly secure, tightly controlled environment; and

6 “(4) should incorporate additional layers of
7 non-visible covert security features up to and includ-
8 ing forensic capability.

9 “(c) STANDARDS FOR PACKAGING.—

10 “(1) MULTIPLE ELEMENTS.—For the purpose
11 of making it more difficult to counterfeit the pack-
12 aging of drugs subject to section 503(b), manufac-
13 turers of the drugs shall incorporate the technologies
14 described in subsection (b) into multiple elements of
15 the physical packaging of the drugs, including blister
16 packs, shrink wrap, package labels, package seals,
17 bottles, and boxes.

18 “(2) LABELING OF SHIPPING CONTAINER.—
19 Shipments of drugs described in subsection (a) shall
20 include a label on the shipping container that incor-
21 porates the technologies described in subsection (b),
22 so that officials inspecting the packages will be able
23 to determine the authenticity of the shipment. Chain
24 of custody procedures shall apply to such labels and
25 shall include procedures applicable to contractual

1 agreements for the use and distribution of the labels,
2 methods to audit the use of the labels, and database
3 access for the relevant governmental agencies for
4 audit or verification of the use and distribution of
5 the labels.”.

Passed the House of Representatives July 25 (legis-
lative day, July 24), 2003.

Attest:

JEFF TRANDAHL,

Clerk.